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09/907,900	07/19/2001	James L. Hartley	0942.285000D	1831

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[REDACTED] EXAMINER

SANDALS, WILLIAM O

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

1636

DATE MAILED: 04/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. 09/907,900	Applicant(s) Hartley et al.
Examiner William Sandals	Art Unit 1636



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM

THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Jan 16, 2003

2a)  This action is FINAL.

2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 52-67

is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideratio

is/are allowed.

5)  Claim(s) \_\_\_\_\_ is/are rejected.

6)  Claim(s) 52-67 is/are objected to.

7)  Claim(s) \_\_\_\_\_

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on Jul 19, 2001 is/are  accepted or  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is:  approved  disapproved by the Examiner

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1)  Notice of References Cited (PTO-892)

4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

5)  Notice of Informal Patent Application (PTO-152)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6

6)  Other: \_\_\_\_\_

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## **DETAILED ACTION**

### *Status of the Claims*

1. Claims 52-67 are pending. Claim 1 has been cancelled by amendment in Paper No. 9, filed January 16, 2003.
2. The restriction of the claims was drawn to Group I, claim 1 and Group II, claims 52-67. The cancellation of claim 1, Group I has made the restriction moot.
3. Claims 53 and 60 stand rejected under 35 USC 112, second paragraph.
4. Claims 52-59, 61, 62, 66 and 67 stand rejected as anticipated under 35 USC 102(e) over US 5,962,255 (Griffiths et al.).
5. Claims 52-63, 66 and 67 stand rejected as anticipated under 35 USC 102(e) over US 5,888,732 (Hartley et al. of record).
6. Claims 52-67 stand rejected as anticipated under 35 USC 102(e) over US 5,851,808 (Elledge et al. of record).

### *Drawings*

7. The drawings as filed on July 19, 2001, have been approved by the draftsman.

### *Claim Rejections - 35 USC § 112*

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 53 and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 53 contains the trademark/trade name PCR. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe polymerase chain reaction and, accordingly, the identification/description is indefinite.

11. Claim 60 recites the limitation "said nucleic acid molecule" in line 1. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

13. Claims 52-59, 61, 62, 66 and 67 are rejected under 35 U.S.C. 102(e) as being anticipated

by US 5,962,255 (Griffiths et al.).

US 5,962,255 (Griffiths et al.) teach a method for cloning an amplified linear nucleic acid by amplifying a nucleic acid template with a first primer comprising a first recombination site and a second primer comprising a second recombination site (*lox* sites), where the first and second recombination sites do not recombine. Recombining the amplified nucleic acid and a vector in the presence of a recombination protein, producing a recombinant vector (product vector). The vector comprises third and fourth recombination sites which will recombine with the first and second recombination sites, as recited in instant claim 52 (see Griffiths at example 6). The amplification is accomplished by polymerase chain reaction (claim 53). The recombinant vector is expressed in a host cell (claims 54-55). The vector comprises a promoter, a restriction site, an origin of replication, a cloning site and a gene (claims 56-59). The nucleic acid is linear (claim 61). The recombination sites may be *lox* or *att* sites (claims 66-67) (see Griffiths et al. at column 19).

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14. Claims 52-63, 66 and 67 are rejected under 35 U.S.C. 102(e) as being anticipated by US 5,888,732 (Hartley et al.).

US 5,888,732 (Hartley et al.) teach a method for cloning an amplified linear nucleic acid by amplifying a nucleic acid template with a first primer comprising a first recombination site and a second primer comprising a second recombination site (*lox* sites), where the first and second recombination sites do not recombine. Recombining the amplified nucleic acid and a vector in the presence of a recombination protein, producing a recombinant vector *in vitro* (product vector). The vector comprises third and fourth recombination sites which will recombine with the first and second recombination sites, as recited in instant claims 52, 60, 62 and 63 (see Hartley et al. at columns 16, 17 and 19). The amplification is accomplished by polymerase chain reaction (claim 53). The recombinant (product) vector is expressed in a host cell ( (see Hartley et al. at example 1). The vector comprises a promoter, a restriction site, an origin of replication, a cloning site and a gene (claims 56-59) (see Hartley et al. at columns 5-7 and 10-11). The nucleic acid is linear (claim 61). The recombination sites may be *lox*, *loxP511* or *att* sites (claims 66-67)(see Hartley et al. at columns 5-7 and 10-11).

15. Claims 52-67 are rejected under 35 U.S.C. 102(e) as being anticipated by US 5,851,808 (Elledge et al.).

US 5,851,808 (Elledge et al.) teach a method for cloning an amplified linear nucleic acid by amplifying a nucleic acid template with a first primer comprising a first recombination site

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and a second primer comprising a second recombination site (*lox* sites), where the first and second recombination sites do not recombine. Recombining the amplified nucleic acid and a vector in the presence of a recombination protein, producing a recombined vector *in vitro* (product vector). The vector comprises third and fourth recombination sites which will recombine with the first and second recombination sites, as recited in instant claims 52, 60, 62 and 63 (see Elledge et al. at examples 4, 5, and 7). The amplification is accomplished by polymerase chain reaction (claim 53). The recombined (product) vector is expressed in a host cell (see Elledge et al. at example 7). The vector comprises a promoter, a restriction site, an origin of replication, a cloning site and a gene (claims 56-59) (see Elledge et al. at examples 4, 5, and 7). The nucleic acid is linear (claim 61). The recombination sites may be *lox*, *loxP511*, *Frt* or *att* sites (claims 62-67)(see Elledge et al. at example 7 and columns 15-16).

#### *Conclusion*

16. Certain papers related to this application are *welcomed* to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Thursday from 8:30 AM to 7:00 PM, EST. If attempts to reach the

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examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Tech Center customer service center at telephone number (703) 308-0198.

William Sandals, Ph.D.

Examiner

April 1, 2003

*Remy Yucel*  
REMY YUCEL, PH.D  
SUPERVISORY PATENT EXAMINER  
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